

REMARKS

The Official Action of October 22, 2003, and the prior art cited and relied upon therein have been carefully reviewed. The claims in the application remain as claims 1-3, 8-10, 16, 17, 26, 27, 37-42, 47, 49-51, 53, 57, 58, 70, 76-78 and 80-85, and these claims define patentable subject matter warranting their allowance. Accordingly, applicants respectfully request favorable reconsideration of the rejection of claims 1-3, 26, 37, 70, 76, 80, 82 and 84, and allowance of the present application.

Acknowledgement by the PTO of the receipt of applicants' papers filed under Section 119 is noted.

Claims 8, 9, 16, 17, 27, 38-44, 47, 49-51, 53, 57, 58, 77, 78, 81, 83 and 85 have not been rejected on the basis of any prior art, and are only objected to as being dependent on a rejected base claim, i.e. as being "allowable if rewritten in independent form..." Applicant accordingly understands that these claims are deemed by the PTO to define novel and unobvious subject matter under §§102 and 103.

Claim 8 has now been rewritten in independent form and therefore claims 8 and all of the claims which depend therefrom either directly or indirectly should now be in

condition for formal allowance consistent with what is stated in the Official Action.

As regards the other claims which are deemed directed to allowable subject matter but which remain in dependent form, applicant respectfully reserves the right to present such claims in independent form at a later date, if necessary or desirable.

Claims 1-3, 26, 37, 70, 76, 80, 82 and 84 have been rejected under §102 as being anticipated by Sarashina USP 4,413,994. This rejection is respectfully traversed.

To make the distinctions of the present invention over Sarashina more clear, claims 1 and 2 have now been amended to specify the feature that the suction means is adapted to **apply suction to the orifice**. Such subject matter is not shown by Sarashina, and therefore it should be clear that Sarashina does not anticipate any of applicant's claims.

The device of Sarashina comprises an annular suction chamber 105 that provides a region of suction around (and not over) a stoma to hold the device in place; for example, see the description at column 1, lines 61 to 65, "[T]hus, the intestinal irrigator 100 is positively retained in position by suction, and the front ends 101a and 103a of the outer and inner cylindrical walls 101 and 103 are held in sealing engagement with the belly of the patient."

The description in Sarashina goes on, "...the suction of the suction chamber 105 is released, and the intestinal irrigator 100 is detached from the belly of the patient with the irrigating tube 110 withdrawn from the artificial anus. Upon lapse of an appropriate time, an open end of a bag... is brought into contact with the belly... irrigation liquid and matters of the intestine are discharged therefrom into the bag."

It is evident, therefore, that the only suction generated in the Sarashina device is for the sole purpose of attaching the device to the belly of the patient. The waste is only evacuated upon removal of the device and, therefore, upon termination of the suction force.

Accordingly, applicant believes it is clear from Sarashina that the Sarashina irrigation device depicted in Figure 1 relies upon the principle of irrigation alone rather than irrigation in conjunction with suction withdrawal of waste from a stoma as defined in the claims of the present invention.

Contrary to Sarashina, the device of the present invention relies upon a combination of irrigation and suction to remove waste from an orifice. The suction is applied to the orifice and not to the skin surrounding the orifice as

described in Sarashina. Accordingly, it is submitted that applicant's claims are clearly novel over Sarashina.

Other than those claims which depend from allowable claim 8 (already discussed above), all of the other claims in the present application depend either directly or indirectly from claim 1 or claim 2, and thus incorporate the subject matter of claim 1 or claim 2. As it has been pointed out above that claims 1 and 2 define novel subject matter over Sarashina, it follows that all of the claims which depend from claims 1 and 2 also define novel subject matter over Saarashina.

It may be briefly also pointed out that Claims 76 and 82 in addition to incorporating the features of claims 1 and 2 respectively also stipulate at item (iv) that suction is applied to the outlet of the chamber to withdraw waste from the orifice, thus further distinguishing these claims from the device of Sarashina.

Applicant respectfully requests withdrawal of the rejection under §102 based on Sarashina.

No rejections have been imposed under §103, and applicant agrees that the claims of the present application would not have been obvious from any known prior art.

As no rejection under §103 has been imposed, applicant need not address the issue of obviousness.

Nevertheless, and for the record, applicant respectfully notes that by simply removing the inner wall 103a of the suction annulus of Sarashina would not have been obvious to a person skilled in the art. Said skilled artisan would understand that the annulus provides a means of attachment to the body and would recognize that the removal of the inner wall would destroy the suction holding the device in place and would be directly contra-indicated by the teaching of the prior art.

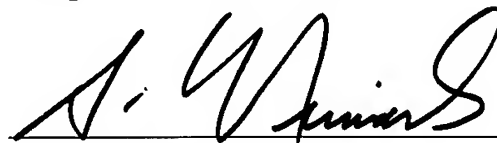
The prior art documents made of record and not relied upon have been noted, along with the implication that such documents are deemed by the PTO to be insufficiently pertinent to warrant their application against any of applicant s' claims.

Favorable reconsideration and allowance are earnestly solicited.

Respectfully submitted,

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